MAY 2 1 2013

510(k) Summary

Solanas® Posterior Stabilization System
Date Prepared: April, 19th, 2013

I	**Company:**	Alphatec Spine, Inc. 5818 El Camino Real Carlsbad, CA 92008. USA
II.	**Contact:**	Trevor J. Denbo Regulatory Affairs Specialist Telephone: 760-494-6951 Fax: 760-431-0289
III.	**Product Trade Name:**	Solanas Posterior Stabilization System
IV.	**Common Name:**	Pedicle screw spinal system
V.	**Classification Name:**	Pedicle screw spinal system
VI.	**Regulation Number:**	888.3050, 888.3070
VII.	**Classification Product Code:**	KWP, MNI, NKB
VIII.	**Predicate Devices:**	Solanas Posterior Stabilization System, K052201 and Modification to Solanas Posterior Stabilization System, K071380

IX. **Description:**

The Solanas Posterior Stabilization System facilitates the surgical correction of spinal deformities by providing temporary internal fixation and stabilization during bone graft healing and/or fusion mass development. Device implants include a range of sizes of bone screws, hooks, rods and bridge assemblies to provide the versatility required for the specific conditions listed in the indications.

The implants are manufactured from surgical grade titanium alloy (Ti-6Al-4V, ASTM F 136) with an electrolytic conversion coating. All hook components are intended for fixation/attachment to the cervical spine only (C1-C7). It is intended that the implants be removed after successful fusion.

X. Indications for Use:

It is intended that this device, in any system configuration, be removed after development of solid fusion mass. Hook components are indicated for use at C1-C7. Polyaxial pedicle screws and offset connectors are limited to the thoracic spine (T1-T3) in treating thoracic conditions only. These screws and offset connectors are not intended to be placed in the cervical spine. The components in the Solanas Posterior stabilization system can be linked to the components in the Zodiac Polyaxial spinal fixation system offered by Alphatec Spine using the axial rod connectors, parallel rod connectors or transitional rods

1. Degenerative disc disease (DDD), defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies.
2. Spondylolisthesis
3. Spinal stenosis
4. Fracture/Dislocation
5. Atlanto/Axial fracture with instability
6. Revision of previous cervical spine surgery
7. Tumors

XI. Summary of the Technological Characteristics:

The technological characteristics, materials, and indications for use of Solanas® Posterior Stabilization System are substantially equivalent to the previously cleared predicate. The subject device differs from the predicate in that the modified hooks contain 7mm and 8mm blades, which is larger than the predicate.

The Solanas Posterior Stabilization System is a rod system designed to improve the stability of the cervical, cervico-thoracic and upper thoracic spine from C1-T3. This titanium alloy (Ti6Al-4V ELI, ASTM F136) system is simple in design and in its application of posterior rod fixation. It contains integrated functioning screws, rods, hooks, and connectors. The laminar hooks are an integral part of this system providing stabilization to the cervical (C1-C7) portion of the spine. These hooks attach to the lamina via the blade portion of the hook on one end and to a rod via a set screw and collar connection on the other end.

XII. Discussion of the Non-clinical Testing:

Mechanical characteristics were examined in accordance to the static anterior/posterior mechanical property measurements of a subassembly as outlined in ASTM F1798. This performance testing was performed comparing the subject and predicate devices per the recognized consensus standards and per the guidance document, *Guidance for Industry and FDA Staff: Spinal System 510(k)s* (2004). This test produced acceptable results and demonstrates that the Solanas Posterior Stabilization System is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Letter Dated: May 21, 2013

Alphatec Spine, Incorporated
% Mr. Trevor J. Denbo
Regulatory Affairs Specialist
5818 El Camino Real
Carlsbad, California 92008

Re: K131119
Trade/Device Name: SOLANAS® Posterior Stabilization System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, MNI, KWP
Dated: April 19, 2013
Received: April 22, 2013

Dear Mr. Denbo:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Laurence D. Coyne -A

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K131119

Device Name: **SOLANAS® Posterior Stabilization System**

Indications For Use:

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6. **Revision of previous cervical spine surgery**
7. **Tumors**

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Ronald P. Jean -S

(Division Sign-Off)
Division of Orthopedic Devices
510(k) Number: K131119